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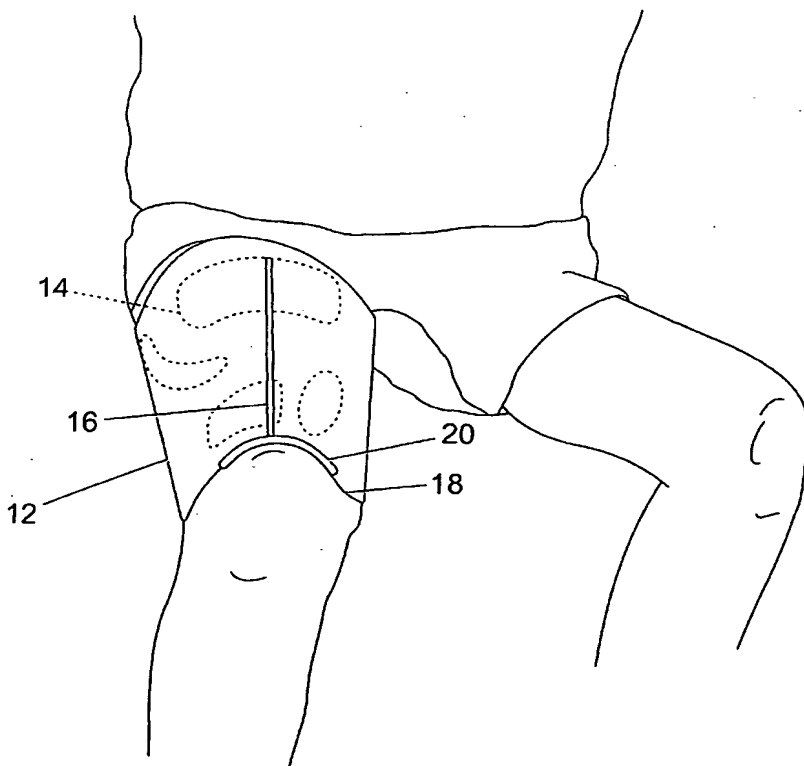
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(54) Title: APPARATUS FOR APPLYING ELECTRICAL CURRENT TO THE NEUROMUSCULAR SYSTEM



(57) Abstract: The invention relates to apparatus for applying electrical current to the quadriceps muscle. The apparatus is in the form of a garment (to be worn on a user's thigh) having a integrated programmable stimulation device including integral electronics, LCD display, user controls and a battery. To ensure accurate and repeatable positioning of the garment, it is shaped such that it locates above the patella. Furthermore, reference lines are provided on the skin facing surface of the garment to assist the user in the accurate placement of skin engaging electrodes. In combination, the features of the invention provides a safe and convenient means of electrically stimulating the quadriceps muscle irrespective of patient size whilst minimising the opportunity for error. Moreover, the invention dispenses with the need to employ a skilled clinician to individually place each electrode.

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<sup>1</sup>  
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1     Apparatus for Applying Electrical Current to the  
2     Neuromuscular System

3

4     The present invention relates to apparatus for  
5     applying electrical current to muscles,  
6     particularly, but not exclusively, to the quadriceps  
7     muscle.

8

9     Electrical stimulation of the quadriceps muscle is  
10    well known. The quadriceps is the most important  
11    muscle to be rehabilitated after an operation on the  
12    knee. It is the strongest extensor of the knee and  
13    improving the force of its contraction after surgery  
14    consequently aids rehabilitation of the other  
15    muscles involved in ambulation.

16

17    The vastus medialis component of the quadriceps  
18    stabilises the patella in the early stages of  
19    walking. After knee surgery, not only can there be  
20    a reflex inhibition of this muscle but there can  
21    also be a temporary disruption of the joint receptor  
22    activity which interferes with the patients

1     proprioceptive feedback. Therefore the quadriceps  
2     muscle needs additional assistance in overcoming  
3     this inhibition and early rehabilitation to aid  
4     stability.

5  
6     Although the quadriceps is a large muscle in the  
7     front of the thigh, the knowledge of a clinical  
8     professional is required in order to accurately  
9     position appropriately sized electrodes according to  
10    patient size to thus ensure effective electrical  
11    stimulation. The professional must ensure that the  
12    correct channels from a stimulator unit are  
13    connected to correct electrodes on the right or left  
14    leg. Whilst previous attempts to produce a fail-  
15    safe garment for electrode application to the body  
16    have succeeded in providing more convenient methods  
17    of electrode application compared to traditional  
18    lead-wired systems, the assistance of a professional  
19    has still been required in the initial set-up stage.

20  
21    A further problem exists in terms of repeatability  
22    in user application of the garment. This is often  
23    inadequate since slight shifts in the position of  
24    the electrode placement from day to day can change  
25    the effectiveness of the stimulation, especially if  
26    the garment is placed over a moving joint.

27  
28    Many muscle groups have a symmetrical group on the  
29    other side of the body across the coronal plane.  
30    These muscle groups are mirror images of each other  
31    and so the electrode placement should take account  
32    of this. This has been achieved in certain garment

1 designs before by producing a mirror image garment  
2 or by turning the existing garment inside out.  
3 Where a stimulator unit and wiring is integrated in  
4 the garment such a solution is not practical since  
5 it would require the user to change the necessary  
6 connections between the stimulator and the  
7 electrodes thus introducing the opportunity for  
8 error.

9  
10 According to a first aspect of the present invention  
11 there is provided apparatus for applying an  
12 electrical current to a neuromuscular system  
13 comprising a garment adapted to cover a portion of a  
14 user's body, a stimulation device for generating a  
15 stimulating current connectable to at least one  
16 electrical contact on said garment, the garment  
17 being shaped to correspond with a particular  
18 anatomical feature to ensure accurate and repeatable  
19 positioning of the garment with respect to the  
20 particular neuromuscular area to be treated.

21  
22 According to a second aspect of the present  
23 invention there is provided apparatus for receiving  
24 an electrical signal from a neuromuscular system  
25 comprising a garment adapted to cover a portion of a  
26 user's body, a receiving device connected to at  
27 least one electrical contact on said garment, the  
28 garment being shaped to correspond with a particular  
29 anatomical feature to ensure accurate and repeatable  
30 positioning of the garment with respect to the  
31 particular neuromuscular area to be monitored.

32

1 Preferably, the garment is marked with one or more  
2 reference lines to aid the accurate and repeatable  
3 positioning of the garment with respect to a  
4 particular neuromuscular area.

5

6 Preferably, the neuromuscular area is the quadriceps  
7 muscle and the anatomical feature is the patella.

8

9 Preferably, the stimulation device is adapted such  
10 that it is interactable with the garment to  
11 determine whether it is a left-limb or right-limb  
12 garment.

13

14 Preferably, the garment has an arcuate shaped edge  
15 at its distal end to correspond with the top of the  
16 patella.

17

18 Preferably, the reference line is alignable with a  
19 notional line extending upwardly from the centre of  
20 the patella.

21

22 Preferably, the garment consists of an undergarment  
23 and an over-garment, the undergarment having at  
24 least one electrical contact on its skin-facing  
25 surface conductively connected to one or more  
26 corresponding electrical contacts on its opposite  
27 surface which, in turn, are conductively connected  
28 to contacts on the over-garment.

29

30 Preferably, the electrical connections between the  
31 undergarment and over-garment are made by stud

1 fasteners which are fixed on and extend through the  
2 undergarment.

3  
4 Preferably, a plurality of electrical contacts are  
5 provided on the undergarment.

6  
7 Preferably, the or each electrical contact on the  
8 undergarment is conductively connectable to one or  
9 more skin engaging electrodes.

10  
11 Preferably, the or each skin engaging electrode is  
12 user replaceable.

13  
14 Preferably, four skin engaging electrodes are  
15 employed.

16  
17 Preferably, at least one skin engaging electrode has  
18 a different surface area from the other skin  
19 engaging electrodes.

20  
21 Preferably, the combined surface area of the  
22 electrodes is at least 300 cm<sup>2</sup>.

23  
24 Preferably, the electrode having the greatest  
25 surface area extends across the upper quadriceps.

26  
27 Preferably, at least one of the remaining electrodes  
28 covers at least part of the lower fibres of the  
29 vastus medialis.

30

1 Preferably, at least one of the remaining electrodes  
2 covers at least part of the lateral fibres of the  
3 quadriceps.

4

5 Preferably, one of the skin engaging electrodes is  
6 generally dog-leg shaped.

7

8 Preferably, at least one of the skin engaging  
9 electrodes is generally rectangular in shape.

10

11 Preferably, printed outlines of the skin engaging  
12 electrodes are provided on the skin-facing surface  
13 of the undergarment to aid accurate positioning of  
14 the electrodes by the user.

15

16 Preferably, the skin engaging electrodes are  
17 displaced circumferentially to establish current  
18 pathways which transect the neuromuscular area.

19

20 Preferably, the stimulation device includes control  
21 means for selectively directing a stimulating  
22 current to one or more of the skin engaging  
23 electrodes.

24

25 Preferably, the control means includes user  
26 programmable software for controlling the duration  
27 of the stimulating pulses and their sequencing  
28 between the skin engaging electrodes.

29

30 Preferably, the control means includes user  
31 programmable software for selecting any subset or  
32 all of the skin engaging electrodes in the garment



1 to form one electrical pole and any other subset or  
2 all of the remaining skin engaging electrodes in the  
3 garment as the opposite electrical pole.

4  
5 Preferably, the control means includes user  
6 programmable software which allows the user to map  
7 control buttons on the garment such that current  
8 applied to the medial and lateral quadriceps muscles  
9 is controllable by medial and lateral control  
10 buttons respectively.

11  
12 Preferably, the or each contact on the over-garment  
13 is conductively connected to the stimulation device  
14 of the first aspect.

15  
16 Alternatively, the or each contact on the over-  
17 garment is conductively connected to the receiving  
18 device of the second aspect.

19  
20 Preferably, the garment is securable to a user's  
21 body by hook and loop fasteners.

22  
23 Preferably, the garment is configurable for use on  
24 the left or right leg.

25  
26 Preferably, the connections between the stimulation  
27 device and the at least one electrical contact on  
28 said garment are preset and non-alterable by the  
29 user.

30  
31 Preferably, the connections between the stimulation  
32 device and the at least one electrical contact on

1 said garment are non-alterable by the user by virtue  
2 of the fact that they are integrated within the  
3 garment itself.

4

5 An embodiment of the present invention will now be  
6 described, by way of example only, with reference to  
7 the following drawings, wherein:

8

9 Fig. 1 shows apparatus for applying current to the  
10 quadriceps (undergarment and over-garment);

11 Fig. 2 shows the inner and outer surfaces of the  
12 undergarment;

13 Fig. 3 shows the inner and outer surfaces of the  
14 over-garment;

15 Fig. 4 shows the positioning of replaceable  
16 electrodes on the leg;

17 Fig. 5 shows the apparatus in use; and

18 Fig. 6 shows the electrode sequencing of the  
19 apparatus.

20

21 Fig. 1 shows apparatus for applying an electrical  
22 current to a neuromuscular system, said system being  
23 the quadriceps muscle, comprising an undergarment 12  
24 provided with reference lines 14 and 16  
25 respectively. A distal end 18 of the undergarment  
26 is provided with an arcuate shaped portion 20.

27

28 The term neuromuscular is to be understood to  
29 include muscles, muscle parts, muscle groups, nerves  
30 or a combination thereof.

31

1 The apparatus therefore locates unambiguously with  
2 an appropriate anatomical landmark. The anatomical  
3 locating means and corresponding anatomical landmark  
4 must be selected such that the variation in  
5 displacement of electrode positions with respect to  
6 the anatomical location means is minimised for  
7 individuals of different size. This allows a common  
8 design to be used by different individuals with  
9 minimal adjustment.

10

11 Typically, a useful anatomical reference is provided  
12 by a "bony" reference point on the body where the  
13 muscle position with respect to such a reference  
14 point is consistent between individuals. According  
15 to the present invention, the muscle and bony  
16 reference point is the quadriceps and the patella  
17 respectively. The patella is a sesamoid bone of the  
18 quadriceps muscle and so, by effectively being part  
19 of this muscle, it has a direct relationship to its  
20 movement. Regardless of the size of the patient,  
21 the lower fibres of the quadriceps insert via the  
22 quadriceps tendon and then into the patella. The  
23 lower lateral fibres insert just above and laterally  
24 with respect to the patella. The vastus medialis  
25 inserts a little lower on the medial side.

26

27 Accordingly, when designing a garment (see Fig. 1)  
28 to assist with quadriceps electrode placement it has  
29 been found that the following combination ensures  
30 correct location in two axes: (i) an anatomical  
31 locating means comprising an arcuate shaped edge 20  
32 corresponding to the upper portion of the patella;

1 and (ii) a reference line 16 through the mid point  
2 of the patellar curve and along the midline of the  
3 thigh.

4  
5 It will be appreciated by those skilled in the art  
6 that the fitting of undergarment 12 to the leg and  
7 positioning it with the aid of the reference line 16  
8 and the arcuate shaped portion 20 can be performed  
9 by the user without any professional assistance.

10

11 Fig. 2 shows both the inner (skin facing) surface 30  
12 and outer surface 32 of an undergarment adapted for  
13 use on the right leg. Reference lines 34 are  
14 provided on the inner surface 30 corresponding to  
15 the shapes of replaceable electrodes A, B, C and D  
16 for contacting the skin (discussed further below  
17 with reference to Fig. 4). Alternative reference  
18 lines 36 are also provided on the inner surface 30.  
19 The reference lines 34 are not intended to be  
20 visible on the outer surface 32 but are shown in  
21 Fig. 2 as dashed lines 34 for clarity.

22

23 Electrical contacts 38 are provided on the inner  
24 surface 30 of the undergarment and are conductively  
25 connected to corresponding electrical contacts 40 on  
26 the outer surface 32.

27

28 Velcro® straps 42 (i.e. hook and loop fasteners) are  
29 provided on either side of the undergarment and an  
30 arcuate shaped portion 44 (corresponding to  
31 reference numeral 20 in Fig. 1) is provided at its  
32 lower end.

1

2 In use, replaceable electrodes for contacting a  
3 user's skin are positioned on the skin facing  
4 surface of the undergarment with the aid of the  
5 reference lines 34. For some users (i.e. because of  
6 their size of other specific requirements)  
7 replaceable electrodes A and D are positioned to  
8 correspond with the alternative reference lines 36.

9

10 The undergarment is then fitted to the user's leg by  
11 wrapping and securing the Velcro® straps 42 around  
12 the thigh and aligning the arcuate shaped portion 44  
13 with the top of the patella. The electrical  
14 contacts 38 on the inner surface 30 therefore make  
15 electrical contact with the replaceable electrodes  
16 which in turn contact the user's skin over the  
17 quadriceps muscle. The replaceable electrodes  
18 electrically connect to the contacts 38 by means of  
19 mating contacts or a conductive adhesive layer.

20

21 The contacts 38 are electrically connected to  
22 contacts 40 on the outer surface 32 of the  
23 undergarment. The electrical contacts 38 and 40  
24 preferably comprise conductive stud fasteners which  
25 are fixed on and extend through the fabric of the  
26 undergarment. The flat surface of the stud fastener  
27 presents on the inner surface 30 whereas a male or  
28 female part of the stud fastener presents on the  
29 outer surface 32.

30

31 The reference lines 34 and 36 and the electrical  
32 contacts 38 are positioned to correspond with

1 anatomical features such that upon correct  
2 application and alignment of the garment to the leg,  
3 electrodes of appropriate size, shape, orientation  
4 and electrical connection are positioned on the leg.  
5

6 Fig. 3 shows both the inner surface 50 and outer  
7 surface 52 of an over-garment which is worn over the  
8 undergarment of Figs 1 and 2. The inner surface 50  
9 is provided with stud fasteners 54 which are  
10 electrically connected to a stimulation device 56.  
11 Control means 58 for controlling the stimulation  
12 device are provided on the outer surface 52 of the  
13 over-garment.  
14

15 In use, the over-garment is attached to the  
16 undergarment via their respective stud fasteners 54  
17 and 40. A conductive path is thereby formed between  
18 the stimulation device 56 and the replaceable  
19 electrodes on a user's skin.  
20

21 The over-garment is a flexible fabric envelope  
22 containing the stimulator electronics and a battery.  
23 The control means 58 comprises an integral Liquid  
24 Crystal Display (LCD) and button control panel  
25 located on the outer surface 52 of the over-garment.  
26 The user controls include two up and down controls  
27 for medial and lateral muscles. The stimulator  
28 internally re-maps these controls depending on  
29 whether it is operating on a left or right  
30 undergarment. For example, on a left undergarment,  
31 the rightmost amplitude control sets the intensity  
32 of the medial muscle, whereas on the right

1 undergarment it is the leftmost amplitude control  
2 which sets the intensity of the medial muscle. This  
3 is particularly important when the sequencing of the  
4 muscle activation is required to recruit medial  
5 before lateral muscles.

6  
7 Fig. 4 shows four replaceable electrodes A, B, C and  
8 D which are positionable within the undergarment  
9 and, in use, contact the user's skin. This figure  
10 illustrates where each electrode typically locates  
11 on the right leg when the undergarment is applied in  
12 accordance with the user instructions. Electrode A  
13 covers the upper quadriceps area while electrodes B  
14 and C together cover the lower quadriceps area.  
15 Electrode C locates medially while B locates more  
16 centrally and extends laterally. Electrode D has a  
17 dog-leg shape and is positioned to recruit the more  
18 lateral fibres of the quadriceps.

19  
20 Electrode A: This is a large electrode in the  
21 shape of a rectangle measuring 20 cm x 10cm (with  
22 rounded corners) positioned so as to extend across  
23 the upper quadriceps as illustrated. The electrode  
24 extends equidistant either side of the mid-thigh  
25 location mark and its lower edge is displaced 20cm  
26 from the midpoint of the patellar locating arcuate  
27 portion described previously. An alternative  
28 position for electrode A is also provided to  
29 accommodate taller users which is 22cm from the  
30 patellar mark. This electrode has a surface area of  
31 approximately 196 cm<sup>2</sup>.

32

1     Electrode B:     This electrode is in the shape of a  
2     rectangle measuring 10 cm x 7.5 cm (again with  
3     rounded corners) positioned so as to extend across  
4     the lateral portion of the quadriceps muscle close  
5     to the patella.   The major midline of this electrode  
6     is 7 cm from the patellar mark while the minor  
7     midline is displaced 4 cm laterally from the midline  
8     locating mark on the garment.   This electrode has a  
9     surface area of approximately 74 cm<sup>2</sup>.

10

11    Electrode C:     This electrode is in the shape of a  
12    rectangle measuring 14cm x 6.5 cm (again with  
13    rounded corners) which extends along the medial  
14    portion of the quadriceps muscle close to the  
15    patella.   The major mid line of the electrode is  
16    displaced 6 cm from the midline locating mark on the  
17    garment and the minor midline of the electrode is  
18    displaced 7 cm from the patellar locating edge.  
19    This electrode has a surface area of approximately  
20    82 cm<sup>2</sup>.

21

22    Electrode D:     This is a small electrode which  
23    locates laterally on the upper leg.   It is  
24    preferably dog-leg in shape and can be used on  
25    either the right or left leg.   This electrode has a  
26    surface area of approximately 57 cm<sup>2</sup>.   An  
27    alternative, more lateral, position for the  
28    electrode is provided on the garment to accommodate  
29    thighs of larger girth.

30

31    In this non-limiting example, the total area of all  
32    four electrodes is approximately 410 cm<sup>2</sup>.   However,



1 it will be appreciated that dimensions of the  
2 electrodes can be varied and are typically greater  
3 than 300 cm<sup>2</sup>. The electrodes are as large as  
4 possible to recruit the target muscle with the  
5 minimum current density at the skin. It is clear  
6 that most of the anterior surface of the thigh is  
7 covered by one or other of the electrodes and this  
8 is very different to the established practice which  
9 favours much smaller electrodes which require more  
10 accurate placement. Using these much larger surface  
11 area electrodes has proved successful in recruiting  
12 the maximum number of muscle fibres whilst  
13 minimising current density at the skin.

14  
15 The relative sizes and positions of electrodes when  
16 in place on the body define the current pathways  
17 which can be created. When electrodes are placed on  
18 a planar body surface then the penetration of the  
19 electric field is not as good as when electrodes are  
20 placed on a curved surface. By choosing electrode  
21 positions which establish current pathways which  
22 transect the body structure then stimulation of  
23 deeper tissue can be achieved. The thigh, in simple  
24 terms, is a cylindrical formation with little  
25 curvature along its length but high curvature around  
26 its circumference. Accordingly, by positioning one  
27 electrode displaced circumferentially from another  
28 electrode located at the anterior thigh midline we  
29 achieve deeper penetration. The appropriate  
30 dimensioning of this displacement with respect to  
31 relevant anatomical markers ensures that selected  
32 nerves are stimulated.

1  
2 The preferred positioning of the replaceable  
3 electrodes is as follows. One large electrode  
4 covering the upper fibres of the quadriceps and the  
5 femoral nerve and (its upper branches). Two lower  
6 electrodes cover the distal quadriceps fibres. The  
7 inner lower electrode is sized and shaped so that it  
8 covers the lower fibres of the vastus medialis.  
9 This gives us the option to zone in on this muscle  
10 separately for part of the rehabilitation. The  
11 fourth electrode is an outer lateral electrode and  
12 lies on the extreme lateral fibres of the quadriceps  
13 and its main function is to direct the impulses from  
14 the combination of electrodes in a different  
15 direction. This electrode is displaced  
16 circumferentially from the anterior thigh midline  
17 and when used in conjunction with some or all of the  
18 other electrodes creates current paths with transect  
19 the thigh thereby stimulating deeper tissue. This  
20 allows rehabilitation of a greater variety of fibres  
21 within the muscle.  
22  
23 The large surface areas of these electrodes allow  
24 for a more comfortable contraction, because the skin  
25 current density is reduced. Furthermore, this  
26 reduces the necessity for precise adjustment of  
27 electrode positioning between individuals.  
28  
29 Fig. 5 shows the apparatus in use whereby the user  
30 can control the stimulation of the quadriceps  
31 muscle.  
32

1     The apparatus comprises an over-garment having an  
2     integrated stimulation device which includes  
3     integrated electronics, an LCD display, user  
4     controls and a battery. The integrated nature of  
5     the electrical connections means that the user does  
6     not have to make individual connections between the  
7     stimulator terminal and each replaceable electrode.  
8     Apart from removing the requirement to select  
9     electrical connections, such a system can  
10    automatically change between left leg and right leg  
11    modes by transposing connections and the mapping of  
12    user controls and display elements.

13

14    While the apparatus may work with a simple single or  
15    dual channel stimulator, it is preferable that the  
16    apparatus is connected to an advanced stimulator, as  
17    more fully explained below. This allows the  
18    selection of any subset of electrodes as one  
19    electrical pole (i.e. as a cathode) and any other  
20    subset as the other electrical pole (i.e. as an  
21    anode) and therefore creates a choice of current  
22    pathways through the thigh.

23

24    The success of traditional Electrical Muscle  
25    Stimulation (EMS) systems depends on the relative  
26    positions of the array electrodes on the body, and  
27    the correct connection to signal sources in the  
28    stimulator. Any errors could lead to a completely  
29    different current path in the body from that  
30    intended. For this reason these techniques are not  
31    suitable for general use with traditional exposed  
32    leadwire systems which are prone to human error.

1 The present apparatus solves this problem by  
2 providing an electrode locating means, and an  
3 electrode connection means within an integrated  
4 tamperproof garment. The electrode selections and  
5 the timing thereof are as follows.

6  
7 The preferred apparatus has an integrated two-  
8 channel electronic muscle stimulation garment  
9 operating with four replaceable skin electrodes.  
10 Preferably, the stimulation signal takes the form of  
11 a modulated pulse train, utilising a symmetric  
12 biphasic pulse with interphase interval, operating  
13 under constant current control. Each stimulation  
14 pulse may be divided into a number of time segments,  
15 called timeslots, and different electrode selections  
16 can be made under software control for each  
17 timeslot.

18  
19 The general effect of this approach is to achieve  
20 larger effective electrode areas by combining the  
21 areas of individual electrodes. This reduces skin  
22 current density for a given stimulation current  
23 level. The effect of dividing the pulse into  
24 timeslots with different electrode selections is to  
25 vary the phase charge seen by each electrode and  
26 therefore the intensity of stimulation associated  
27 with each electrode.

28  
29 Where electrodes are combined to form an anode or  
30 cathode, then the current density at the skin is  
31 reduced, thereby reducing skin sensation compared to  
32 the situation of using only one of the electrodes.

1     that channel 1 is operable by the left hand  
2     amplitude controls when fitted on a right leg  
3     undergarment, and by the right hand amplitude  
4     control when fitted on a left leg undergarment. In  
5     this way, the medial part of the muscle is always  
6     operable by the medial amplitude control, whereas  
7     the lateral muscle group is always operable by the  
8     lateral amplitude control.

9  
10    A further example of electrode sequencing together  
11    with the current patterns at each electrode is  
12    provided in the second table in Fig. 6 with the  
13    corresponding current patterns for each electrode  
14    shown underneath. (The current patterns are not to  
15    scale in either time or current amplitude)

16  
17    Various modifications and improvements may be made  
18    without departing from the scope of the present  
19    invention.

20  
21    For example, an alternative to the arcuate shaped  
22    portion which corresponds with the shape of the  
23    patella could be a donut shaped locator at the  
24    distal end of the undergarment. However this  
25    design, as with any thigh garment with a knee  
26    splint, would tend to pull on the undergarment  
27    proximally when the knee joint flexes.

28  
29    Two versions of the undergarment could be provided,  
30    one for the right and one for the left leg. An  
31    identical array of stud fasteners would be provided  
32    on either type however a different subset of

1  
2 5. Apparatus according to any preceding claim  
3 wherein, the stimulation device is adapted such that  
4 it is interactable with the garment to determine  
5 whether it is a left-limb or right-limb garment.  
6

7 6. Apparatus according to claim 4 or 5 wherein,  
8 the garment has an arcuate shaped edge at its distal  
9 end to correspond with the top of the patella.  
10

11 7. Apparatus according to any of claims 4 to 6  
12 wherein, the reference line is alignable with a  
13 notional line extending upwardly from the centre of  
14 the patella.  
15

16 8. Apparatus according to any of claims 1 to 7  
17 wherein, the garment consists of an undergarment and  
18 an over-garment, the undergarment having at least  
19 one electrical contact on its skin-facing surface  
20 conductively connected to one or more corresponding  
21 electrical contacts on its opposite surface which,  
22 in turn, are conductively connected to contacts on  
23 the over-garment.  
24

25 9. Apparatus according to claim 8 wherein, the  
26 electrical connections between the undergarment and  
27 over-garment are made by stud fasteners which are  
28 fixed on and extend through the undergarment.  
29

30 10. Apparatus according to claim 8 or 9 wherein, a  
31 plurality of electrical contacts are provided on the  
32 undergarment.

1 contacts would be used for the left and right  
2 versions. An undergarment would be factory  
3 configured for left or right use by electrically  
4 linking one stud fastener in one of two alternative  
5 positions. This would allow the stimulator  
6 electronics to detect which undergarment is  
7 connected and thereby direct the appropriate signals  
8 to each element of the stud array. Alternatively,  
9 unused stud fasteners could be insulated with an  
10 insulating cover.

11  
12 While the preferred apparatus includes the over-  
13 garment having an integrated stimulator device, it  
14 could be adapted for use with various conventional  
15 electrical stimulation units. A simple single or  
16 dual channel stimulator device could be connected to  
17 the appropriate electrodes using, for example,  
18 leadwires terminating in stud faster contacts. For  
19 general quadriceps rehabilitation both channels  
20 would be used.

21  
22 In the case where a clinician needs to zone in on  
23 extra rehabilitation of the vastus medialis the  
24 medial channel is used alone. When both channels  
25 are used there is a default feature that brings in  
26 the contraction of the vastus medialis before the  
27 rest of the bulk of the quadriceps. This is  
28 particularly useful for the person with an unstable  
29 patella. If the patella is prone to dislocation it  
30 will invariably be in the lateral direction. In this  
31 embodiment the patella is pulled slightly inwards  
32 and then upwards, ensuring stability of the patella.

1  
2 While the electrode configuration described has  
3 several advantages it is also possible to use  
4 smaller electrodes of conventional round and/or  
5 rectangular shape. Accurate location of such  
6 electrodes can still be achieved by a suitable  
7 garment which includes the anatomical reference  
8 means described (i.e. the patellar location arcuate  
9 portion). The apparatus may include at least one  
10 electrode and may include an array of electrodes  
11 which will all locate correctly if referenced to the  
12 locating means.

13  
14 Any form of electrical therapy or biological signal  
15 detection could be applied to this garment such as  
16 TENS, EMG etc. Indeed, a combined dual function  
17 stimulation and receiving device could be  
18 incorporated into the garment (i.e. a combination of  
19 the first and second aspects of the invention).

20  
21 Garments for other muscle groups in the body could  
22 also be included provided there was a fixed  
23 relationship between the locating surface anatomical  
24 feature and the intended muscle, muscle group or  
25 nerve to this group. Examples of this may include  
26 the reliable location of the common peroneal nerve  
27 just below the fibular head or the ulnar nerve  
28 behind the medial condyle of the humerus. There can  
29 also be a specific relationship between anatomical  
30 features and the movements of a muscle whether it  
31 displaces with movement or simply shortens in an  
32 isometric contraction.



1     CLAIMS

2

3     1.   Apparatus for applying an electrical current to  
4     a neuromuscular system comprising a garment adapted  
5     to cover a portion of a user's body, a stimulation  
6     device for generating a stimulating current  
7     connectable to at least one electrical contact on  
8     said garment, the garment being shaped to correspond  
9     with a particular anatomical feature to ensure  
10    accurate and repeatable positioning of the garment  
11    with respect to the particular neuromuscular area to  
12    be treated.

13

14    2.   Apparatus for receiving an electrical signal  
15    from a neuromuscular system comprising a garment  
16    adapted to cover a portion of a user's body, a  
17    receiving device connected to at least one  
18    electrical contact on said garment, the garment  
19    being shaped to correspond with a particular  
20    anatomical feature to ensure accurate and repeatable  
21    positioning of the garment with respect to the  
22    particular neuromuscular area to be monitored.

23

24    3.   Apparatus according to claim 1 or 2 wherein,  
25    the garment is marked with one or more reference  
26    lines to aid the accurate and repeatable positioning  
27    of the garment with respect to a particular  
28    neuromuscular area.

29

30    4.   Apparatus according to any preceding claim  
31    wherein, the neuromuscular area is the quadriceps  
32    muscle and the anatomical feature is the patella.

1

2 11. Apparatus according to any of claims 7 to 9  
3 wherein, the or each electrical contact on the  
4 undergarment is conductively connectable to one or  
5 more skin engaging electrodes.

6

7 12. Apparatus according to claim 11 wherein, the or  
8 each skin engaging electrode is user replaceable.

9

10 13. Apparatus according to claim 11 or 12 wherein,  
11 four skin engaging electrodes are employed.

12

13 14. Apparatus according to claim 13 wherein, at  
14 least one skin engaging electrode has a different  
15 surface area from the other skin engaging  
16 electrodes.

17

18 15. Apparatus according to claim 13 or 14 wherein,  
19 the combined surface area of the electrodes is at  
20 least 300 cm<sup>2</sup>.

21

22 16. Apparatus according to claim 14 wherein, the  
23 electrode having the greatest surface area extends  
24 across the upper quadriceps.

25

26 17. Apparatus according to claim 16 wherein, at  
27 least one of the remaining electrodes covers at  
28 least part of the lower fibres of the vastus  
29 medialis.

30

1 18. Apparatus according to claim 16 wherein, at  
2 least one of the remaining electrodes covers at  
3 least part of the lateral fibres of the quadriceps.  
4

5 19. Apparatus according to any of claims 11 to 18  
6 wherein, one of the skin engaging electrodes is  
7 generally dog-leg shaped.  
8

9 20. Apparatus according to any of claims 11 to 19  
10 wherein, at least one of the skin engaging  
11 electrodes is generally rectangular in shape.  
12

13 21. Apparatus according to any of claims 11 to 20  
14 wherein, printed outlines of the skin engaging  
15 electrodes are provided on the skin-facing surface  
16 of the undergarment to aid accurate positioning of  
17 the electrodes by the user.  
18

19 22. Apparatus according to any of claims 11 to 21  
20 wherein, the skin engaging electrodes are displaced  
21 circumferentially to establish current pathways  
22 which transect the neuromuscular area.  
23

24 23. Apparatus according to any of claims 11 to 22  
25 wherein, the stimulation device includes control  
26 means for selectively directing a stimulating  
27 current to one or more of the skin engaging  
28 electrodes.  
29

30 24. Apparatus according to claim 23 wherein, the  
31 control means includes user programmable software  
32 for controlling the duration of the stimulating

1 pulses and their sequencing between the skin  
2 engaging electrodes.

3

4 25. Apparatus according to claim 23 or 24 wherein,  
5 the control means includes user programmable  
6 software for selecting any subset or all of the skin  
7 engaging electrodes in the garment to form one  
8 electrical pole and any other subset or all of the  
9 remaining skin engaging electrodes in the garment as  
10 the opposite electrical pole.

11

12 26. Apparatus according to any of claims 23 to 25  
13 wherein, the control means includes user  
14 programmable software which allows the user to map  
15 control buttons on the garment such that current  
16 applied to the medial and lateral quadriceps muscles  
17 is controllable by medial and lateral control  
18 buttons respectively.

19

20 27. Apparatus according any of claims 8 to 26 when  
21 dependent on claim 1 wherein, the or each contact on  
22 the over-garment is conductively connected to the  
23 stimulation device.

24

25 28. Apparatus according to any of claims 8 to 27  
26 when dependent on claim 2 wherein, the or each  
27 contact on the over-garment is conductively  
28 connected to the receiving device.

29

30 29. Apparatus according to any preceding claim  
31 wherein, the garment is securable to a user's body  
32 by hook and loop fasteners.

1

2 30. Apparatus according to any preceding claim  
3 wherein, the garment is configurable for use on the  
4 left or right leg.

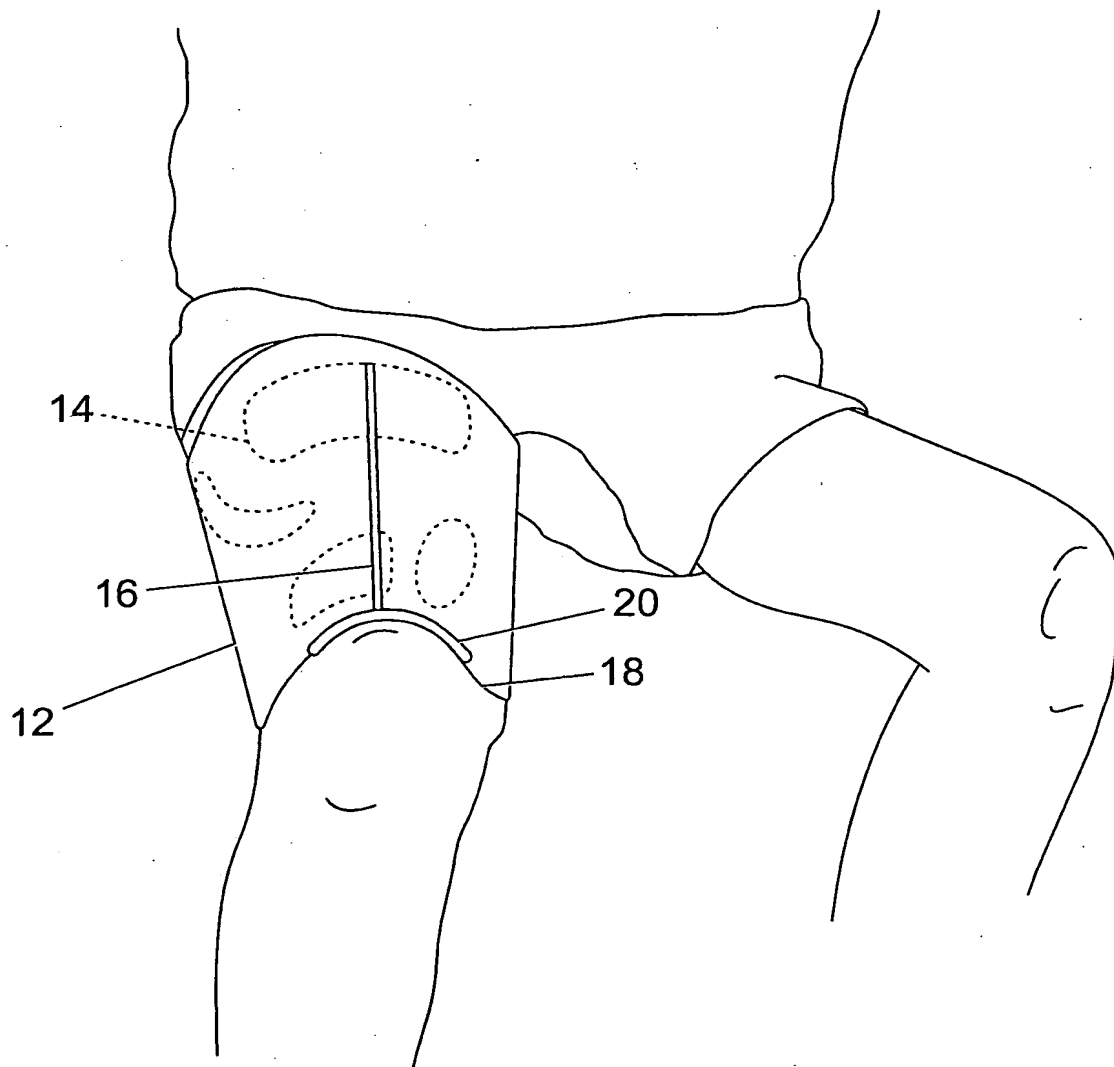
5

6 31. Apparatus according to any preceding claim  
7 wherein, the connections between the stimulation  
8 device and the at least one electrical contact on  
9 said garment are preset and non-alterable by the  
10 user.

11

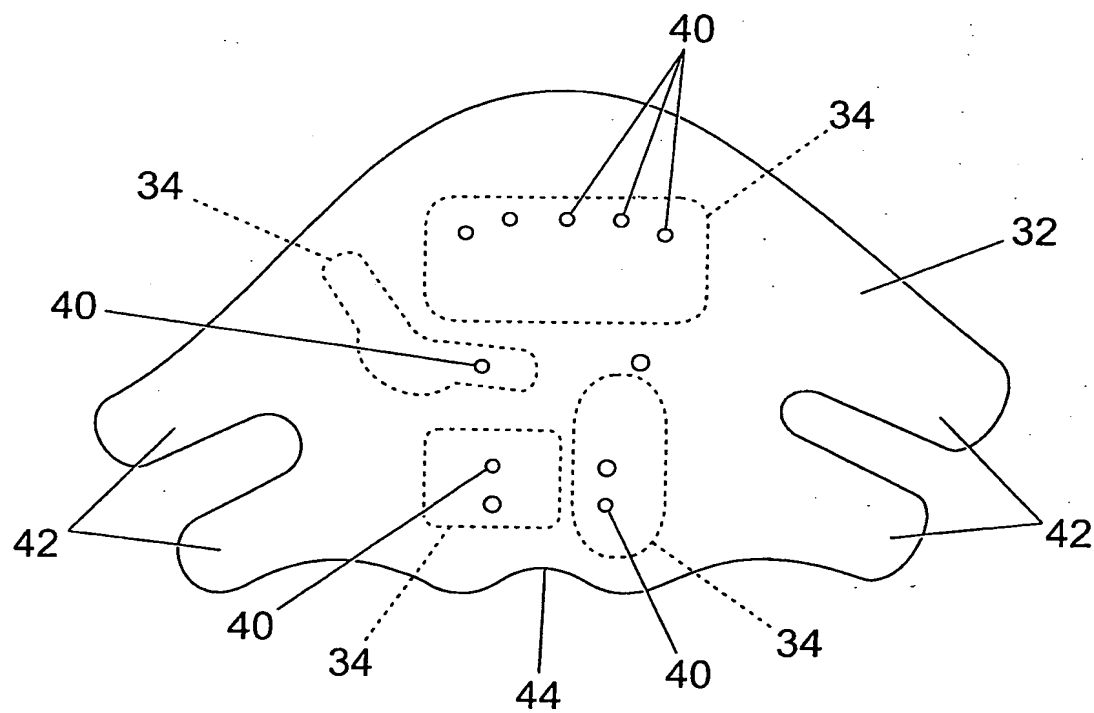
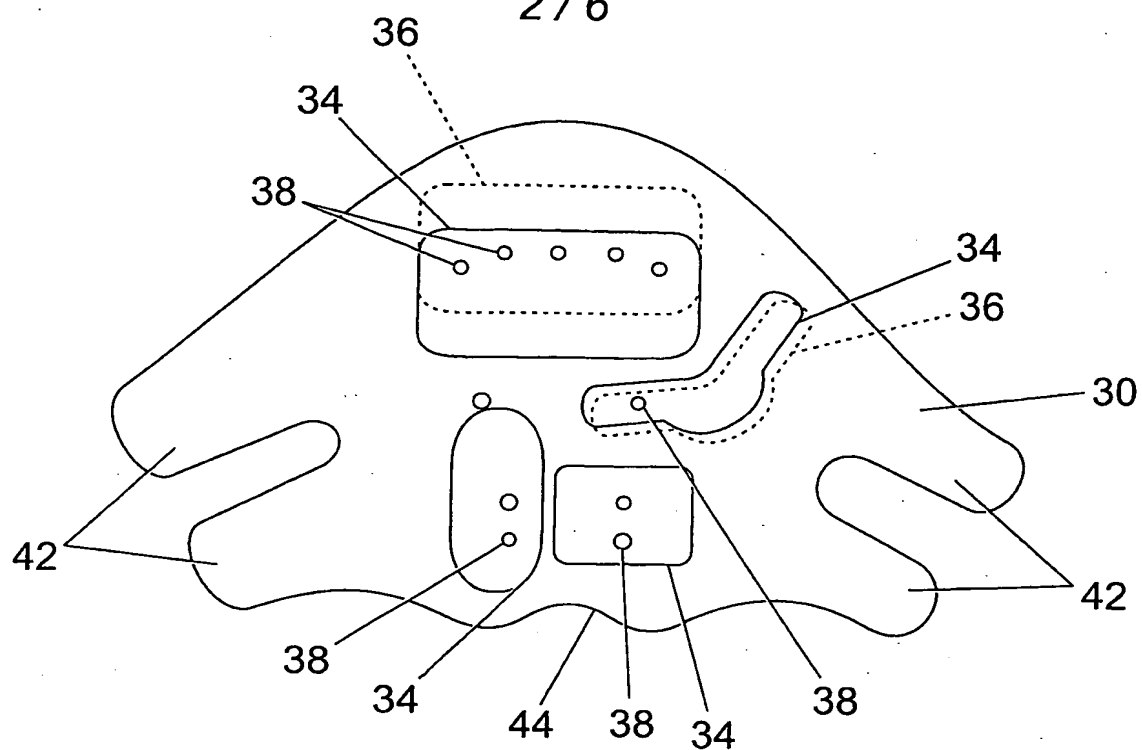
12 32. Apparatus according to claim 31 wherein, the  
13 connections between the stimulation device and the  
14 at least one electrical contact on said garment are  
15 integrated within the garment itself.

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*Fig. 1*

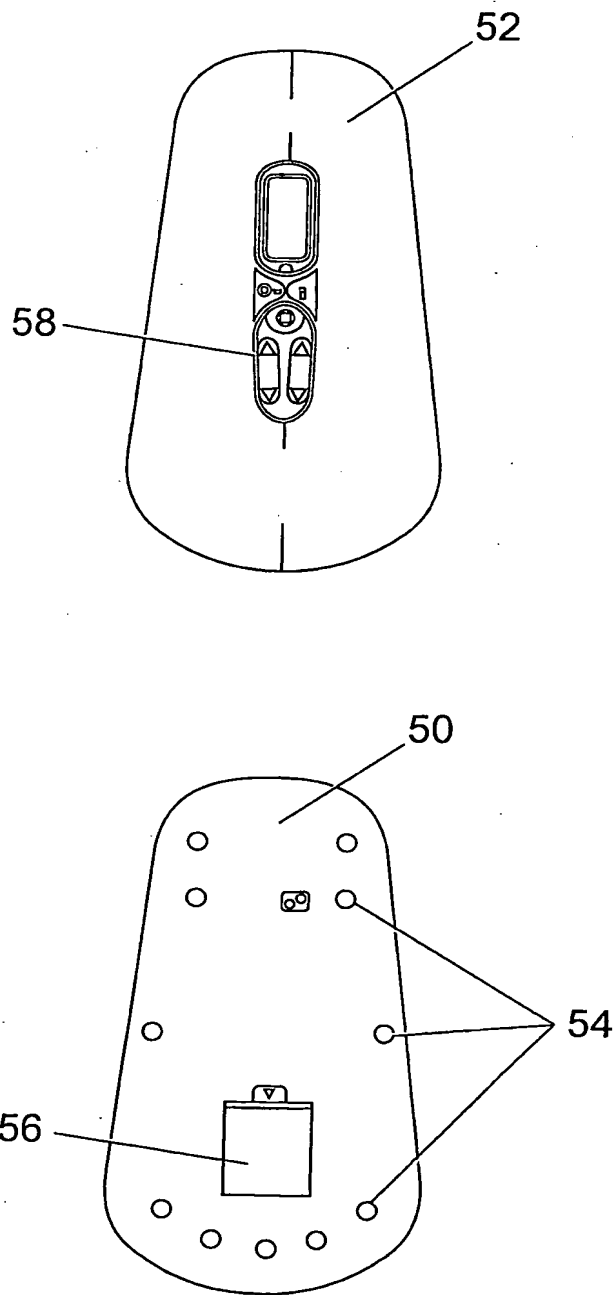
2 / 6



*Fig. 2*

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*Fig. 3*



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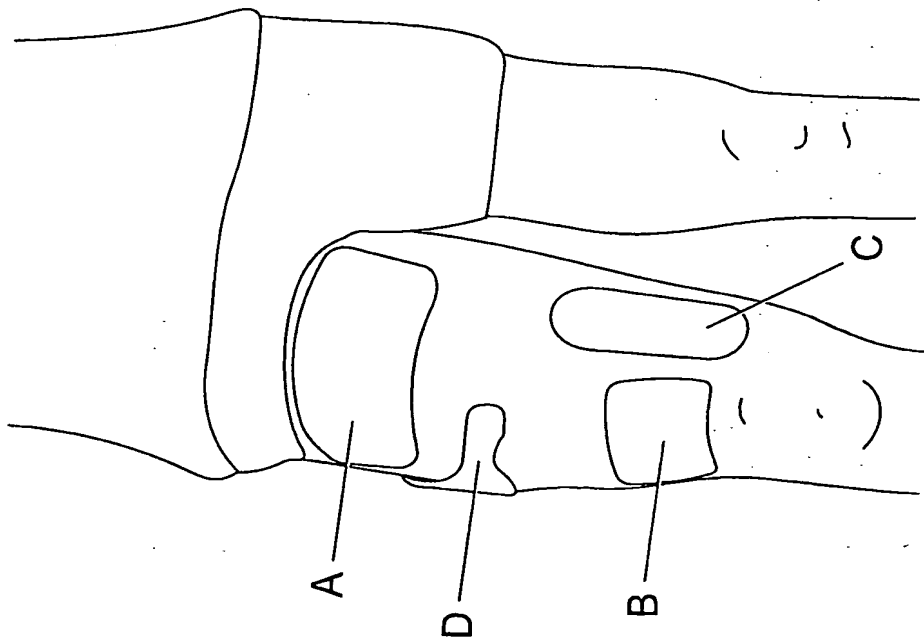
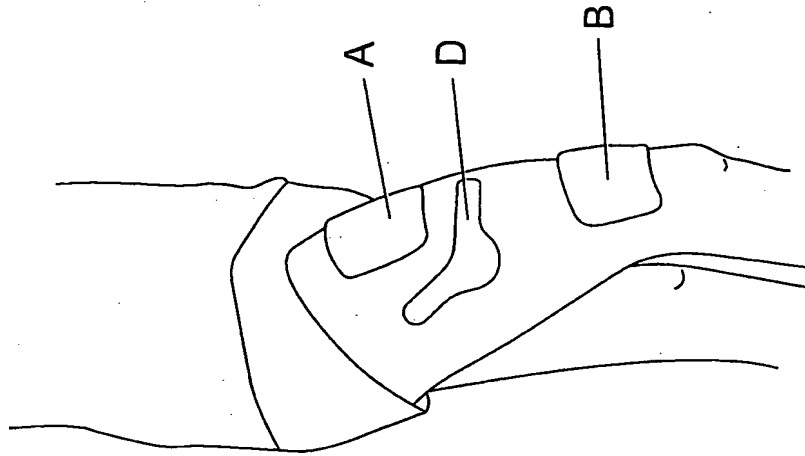
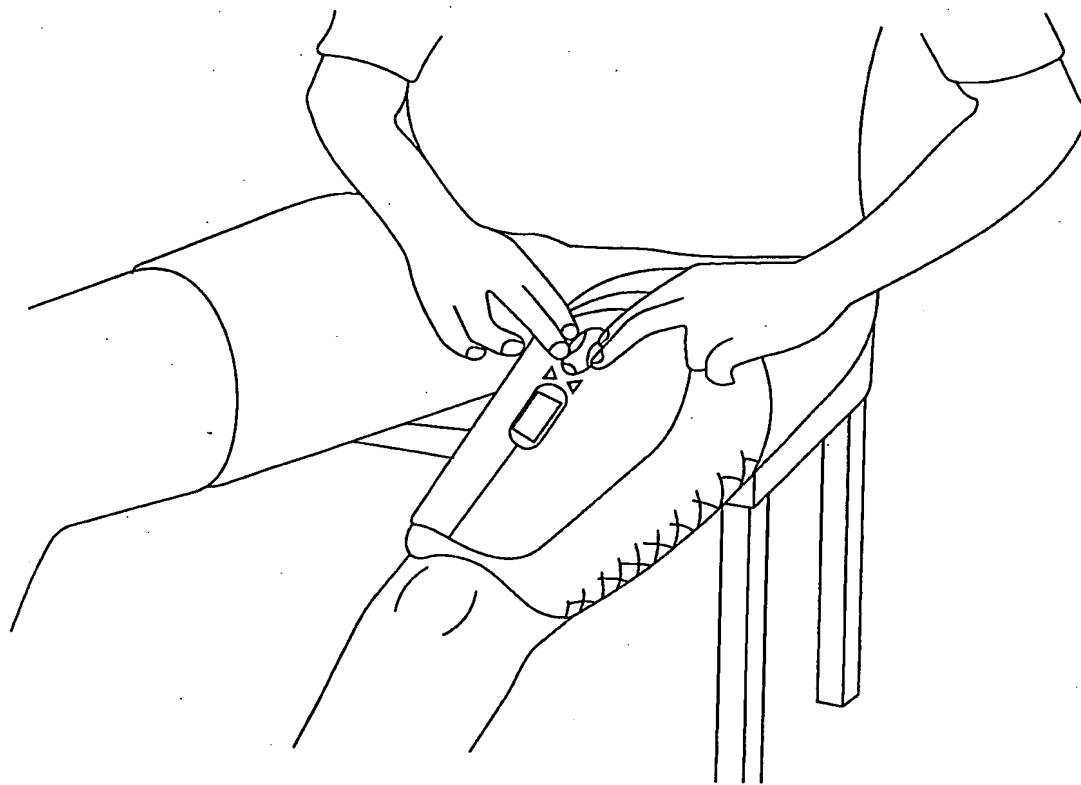


Fig. 4

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*Fig. 5*

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Pad	CH1 TS1	CH2 TS1	CH2 TS2
A	H	L	L
B	H	H	X
C	L	H	X
D	H	X	H
Duration uS	100	300	100

CH1	Timeslot 1	Timeslot 2
A	Hi	Hi
B	Hi	Hi
C	Lo	Lo
D	Hi	Hi
Duration	100uS	100uS

CH2	Timeslot 1	Timeslot 2
A	Lo	Lo
B	Hi	X
C	Hi	X
D	X	Hi
Duration	600uS	200uS

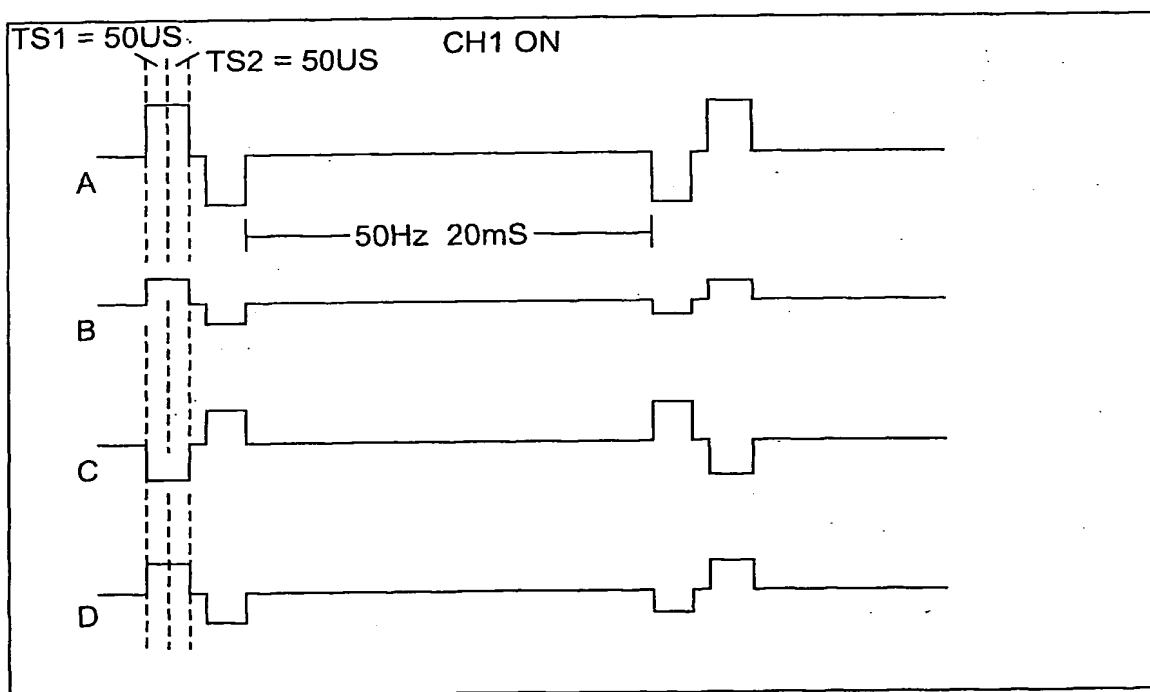


Fig. 6

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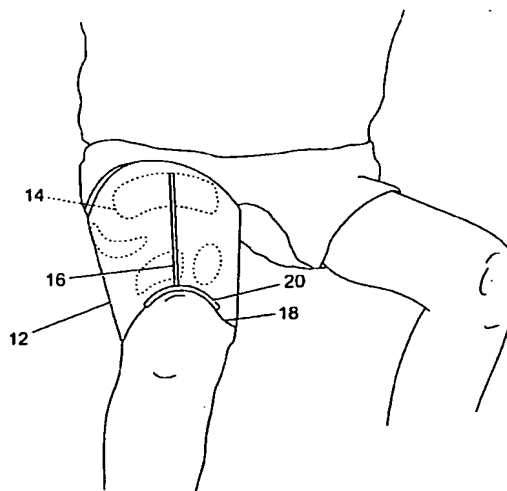
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[Continued on next page]

(54) Title: APPARATUS FOR APPLYING ELECTRICAL CURRENT TO THE NEUROMUSCULAR SYSTEM



(57) Abstract: The invention relates to apparatus for applying electrical current to the quadriceps muscle. The apparatus is in the form of a garment (to be worn on a user's thigh) having an integrated programmable stimulation device including integral electronics, LCD display, user controls and a battery. To ensure accurate and repeatable positioning of the garment, it is shaped such that it locates above the patella. Furthermore, reference lines are provided on the skin facing surface of the garment to assist the user in the accurate placement of skin engaging electrodes. In combination, the features of the invention provides a safe and convenient means of electrically stimulating the quadriceps muscle irrespective of patient size whilst minimising the opportunity for error. Moreover, the invention dispenses with the need to employ a skilled clinician to individually place each electrode.



**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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EPO-Internal, PAJ, WPI Data

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X	WO 02/074109 A (BMR RES & DEV LTD ; CROWE LOUIS (IE); MONLEY SEAMUS (IE); WALSH KEVIN) 26 September 2002 (2002-09-26) abstract; figures 1-18	1, 3, 5, 8-23, 27, 30-32
Y	page 13, line 27 - page 23, line 21	4, 6, 7, 24-26, 28, 29
X	US 2003/060740 A1 (FAGHRI POURAN D) 27 March 2003 (2003-03-27) abstract; figure 4 paragraphs '0034!', '0037!', '0041!'	1, 3, 4, 7
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